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Érvényes Ügyszám: P0104993 MSZH e-laistrom

Bejelentés napja: 1999.10.26

Közzététel napja: 2002.05.28

HU PO104993

Uniós elsőbbség: US60106739 - 1998.11.02

PCT bejelentés száma: US9925244 PCT közzététel száma (WO): 0025753

NSZO: A61K-009/24

Cím: Eljárás és eszköz hatóanyagok kontrollált bevitelére

Angol cim: METHOD AND DEVICE FOR CONTROLLED DELIVERY OF ACTIVE

AGENTS

Bejelentő: ALZA Corporation, Mountain View, Kalifornia (US)

Feltaláló: Yam, Noymi, Sunnyvale, Kalifornia (US) Bhatt, Padmanabh, Saratoga, Kalifornia (US)

Cruz, Evangeline G., Hayward, Kalifornia (US)

Képviselő: Szabó Zsolt, DANUBIA Szabadalmi és Védjegy Iroda Kft., Budapest (HU)







Kivonat (közzétételi): A találmány tárgya hatóanyagot tartalmazó dózisforma (1), valamint kompresszált gyógyszerkészítményt, féligáteresztő falat (2) és tolófázist (5) tartalmazó dózisformából (1) hatóanyag ürülésének elősegítésére szolgáló eljárás.

A találmány szerinti dózisforma (1) tartalmaz űreget (3) meghatározó, legalább egy féligáteresztő tartománnyal és anyagában kialakított vagy kialakítható kiömlönyílással (4) rendelkező falat (2); az üregben (3) a kiömlőnyílástól (4) távol a fal (2) féligáteresztő tartományával közlekedőn elrendezett tágulásra képes tolófázist (5); az üregben (3) a kiömlönyílással (4) szomszédosan, a tágulásra képes tolófázissal (5) közvetlenül vagy közvetve érintkezőn elrendezett hatóanyagfázist (6); továbbá a fal (2) belső felülete és legalább az üregben (3) lévő hatóanyagfázis (6) külső felülete között elrendezett ürülést segítő fázist (7).

A találmány szerinti dózisforma ürülést segítő fázissal (7) bevont kompresszált

gyógyszerkészítményt tartalmaz.

A szóban forgó eljárás lényege, hogy a féligáteresztő fal (2) és a kompresszált gyógyszerkészítmény között ürülést segítő fázist (7) rendeznek el.

\*\*\* ABRA Frame254 \*\*\*\* \*\*\* ABRA Frame253 \*\*\*\*

## Intézkedések

4. Nemzetközi bejelentés közzététele (A2) (QJ)

Intézkedés kelre: 2002.03.27 meghirdetése: 2002.05.28 (BB9A Szabadalmi bejelentések közzététele)

9. Értesítés újdonságkutatás elvégzéséről (A3) (RV)

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Intézkedés kelte: 2003.01.27 meghirdetése: 2003.02.28 (EC9A Külön tájékoztatás újdonságkutatásról)

12. Ideiglenes szabadalmi oltalom újra érvénybe helyezése(2) (El) ref.: 11 Intézkedés kelte: 2003.06.25 árvétele: 2003.06.26 meghirdetése: 2003.07.28 (NF4A Szabadalmi oltalom újra érvénybe helyezése)

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. Device for controlled delivery of high drug-loading compositions includes a flow-promoting layer between the semi-permeable... Page 1 of 5

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Derwent Record

Device for controlled delivery of high drug-loading compositions includes a flow-promoting layer between the semi-permeable layer and the drug layer P Derwent Title:

POriginal Title:

图 WO0025753A2: CONTROLLED DELIVERY OF ACTIVE AGENTS

Other publications from ALZA CORP (ALZA)... ALZA CORP Standard company BHATT P Individual CRUZ E Individual YAM N Individual PAssignee:

BHATT P; CRUZ E; CRUZ E G; YAM N; @Inventor:

**A61K 0)00 ; A61K 9)20 ; A61K 9)22 ; A61K 9)24 ;** A61K 9)44 ; A61K 31/496 ; A61K 47/02 ; A61K 47/10 ; A61K 47/12 ; A61K 47/14 ; A61K 47/13 ; A61K 47/38 ; A61K 47 2000-365362 / 200380 P Accession/ PIPC Code:

A96; B07; A11; A25; P Derwent Classes:

excluding K, B, Ra), B07-D03(Pyrrolidine), B07-D05(Piperidine), B12-M03(Emulsion), B12-M10A (Polyethers), B04-N02(Animal protein/polypeptide (No sequence)), B05-A01B(Group 1a, 2a, 3a A12-V01 (Medicines, pharmaceuticals), B04-C02A(Cellulose and derivatives), B04-C03C Sustained release), B14-J01A1(Antidepressant) Manual Codes:

a) an outer wall which is semipermeable (or partially semipermeable) having an exit orifice formed or formable and which (WO0025753A) Novelty - Use of a flow-promoting layer in a controlled delivery device to minimize drug retention is new. Detailed Description - Controlled delivery dosage form (I) comprises: 8 Derwent

d) a flow-promoting layer interposed between the inner surface of the outer wall and at least the external surface of the drug c) a drug layer located in the cavity adjacent to the exit orifice and in direct or indirect contact with the expandable layer, b) an expandable layer located in the cavity distal to the exit orifice;

ACTIVITY - None given.

MECHANISM OF ACTION - None given.

Luse - ()) are particularly useful for controlled release of drugs in a high-loading oral dosage form for e.g. once-a-day administration. Incorporation of a flow-promoting layer enhances the smooth delivery of the drug by providing less friction at the interface between the drug composition and the semipermeable wall.

Advantage - The flow-promoting layer provides enhanced editory of the drug composition reducing the amount of residual drug remaining undispensed in the device. Consequently the convention of adding extra drug to compensate for that undispensed is unnecessary, resulting in disage forms which are physically smaller and more easy to swallow.

P Family:

. Dwg.0/0					
PoF Patent	Pub. Date	Derwent Update	Pages	Language	PC Code
5753A2 *	2000-05-11	200031	26	English	A61K 9/24
ď	(N) AE AL AM AT AU AZ BA BE KE KG KP KR KZ LC LK LR LS	(N) AE AL AM AT AU AZ BA BB BG BR BY CA CH CN CR CU CZ DE DK DM EE ES FIGB GD GE GH GM HR HU IDIL. IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX NO NZ PL PT RO RU SD SE SG SI SK SL TJ TM TR TT TZ	CZ DE DK DM MW MX NO NZ	EE ES FIGB GD GE ( PL PT RO RU SD SE	SH GM HR HU ID IL IN IS JP SG SI SK SL TJ TM TR TT TZ
	UA UG UZ VN YU ZA ZW (R) AT BE CH CY DE DK EA E	JA UG UZ VN YU ZA ZW R) AT BE CH CY DE DK EA ES FI FR GB GH GM GR IE IT KE LS LU MC MW NL OA PT SD SE SL SZ TZ UG ZW	E LS LU MC MV	VNL OA PT SD SE SL	SZ TZ UG ZW
Local appls.:	WO1999US0025244 Fil	Local appls.: WO1999US0025244 Filed:1999-10-26 (99WO-US25244)	JS25244)		
☑ NZ0511465A =	2003-10-31	200380		English	A61K 9/24
Local appls.:	Local appls.: Based on WO00025753 (WO 200025753) NZ1999000511465 Filed:1999-10-26 (99N WO1999US0025244 Filed:1999-10-26 (96	Based on WO00025753 (WO 200025753) NZ1999000511465 Filed:1999-10-26 (99NZ-0511465) WO1999US0025244 Filed:1999-10-26 (99WO-US25244)	11465) JS25244)	-	
JP2002528486W =	2002-09-03	200273	49	English	A61K 9/22
Local appls.:	Local appls.: Based on W <u>000025753</u> (WO 200025753) WO1999U <u>S0025244</u> Filed:1999-10-26 (99 JP200000579195 Filed:1999-10-26 (200	Based on WO00025753 (WO 200025753) WO1999US0025244 Filed:1999-10-26 (99WO-US25244) JP2000000579195 Filed:1999-10-26 (2000JP-0579195)	JS25244) 1579195)		
☑ ZA0103524A =	2002-07-31	200271	71	English	A61K 0/00
Local appls.:	ZA2001000003524 File	Local appls.: ZA2001000003524 Filed:2001-05-02 (2001ZA-0003524)	0003524)		
<b>M</b> HU0104993A2 =	HU0104993A2 = 2002-05-28 200249	200249		English	A61K 9/24
Local appls.:	Local appls.: Based on WO00025753 (WO 200025753) HU2001000004993 Filed:1999-10-26 (200 WO1999US0025244 Filed:1999-10-26 (96	Based on WO00025753 (WO 200025753) HU20010000004993 Filed:1999-10-26 (2001HU-0004993) WO1999US0025244 Filed:1999-10-26 (99WO-US25244)	-0004993) US25244)		
☑ US20020048600A1	= 2002-04-25	200233	25	English	A61K 9/20
Local appls.:	US2001000001116 File Cont of US1999000430 Provisional US1998000	Local appls.: US2001000001116 Filed.2001-11-27 (2001US-0001116) Cont of <u>US1999000430837</u> Filed.1999-11-01 (99US-0430837) Provisional US1998000106739P Filed.1998-11-02 (98US-108739P)	.0001116) 99US-04308 -02 (98US-1	37) 06739P)	
<b>№</b> US6368626 =	2002-04-09	200227	24	English	A61K 9/22

Local appls.: US1999000430837 Filed:1999-11-01 (99US-0430837)

ď	rovisional US1998000106739	Provisional US1998000106739P Filed:1998-11-02 (98US-106739P)	6739P)	
MX1004371A1 =	2002-03-01	200362	Spanish	A61K 9/24
:: S	Local appls.: Based on WO00025753 (WO 200025753) MX2001000004371 Filed:2001-05-02 (2001MX-0004371) WO1999US0025244 Filed:1999-10-26 (99WO-US25244)	200025753) 1-05-02 (2001MX-0004371) 39-10-26 (99WO-US25244)		
<b>V</b> CN1325301A =	2001-12-05 200223	200223	English	A61K 9/24
Local appls:: C	Local appls.: CN1999000812981 Filed:1999-10-26 (99CN-0812981)	9-10-26 (99CN-0812981)		
₩ EP1126827A2 =	2001-08-29 200150	200150	English	A61K 9/24
Des. States: (R	Des. States: (R) AT BE CH CY DE DK ES FIFR GB GR IE IT LI LU MC NL PT SE	GR IE IT LI LU MC NL PT SE		
Local appls.: B	Local appls.: Based on WO00025753 (WO 200025753) WO1999U50025254 Filed:1995-10-26 (99WO-US25244) PUCLOSOMORT 340 Filed:1908-11-26 (99FP-1951310)	200025753) 99-10-26 (99WO-US25244) 9-10-26 (99EP-0971310)		
4	200000000000000000000000000000000000000			A 0/0 /140 V
KR1075676A =	2001-08-09	200211	English	401N 3/24
Local appls.: K	Local appls.: KR2001000705529 Filed:2001-05-02 (2001KR-0705529)	1-05-02 (2001KR-0705529)		
NO0102168A =	2001-06-13	200141	ON_ON	A61K 9/24
Local appls:: N	Local appls:: NO2001000002168 Filed:2001-05-02 (2001NO-0002168) WO1999US0025244 Filed:1999-10-26 (99WO-US25244)	r1-05-02 (2001NO-0002168) 99-10-26 (99WO-US25244)		
<b>M</b> AU0012385A =	2000-05-22	200040	English	A61K 9/24
pls.: E	Local appls.: Based on WO00025753 (WO 200025753)	200025753)		

# Show legal status actions PINPADOC

AU2000000012385 Filed:1999-10-26 (2000AU-0012385)

&Claims: Legal Status:

1.. A dosage form for an active agent comprising: a wall defining a cavity, the wall having an exit orifice formed or formable therein and at least a portion of the wall being semipermeable; an expandable layer located within the cavity remote from the adjacent the exit orifice and in direct or indirect contacting relationship with the expandable layer, and a flow-promoting layer interposed between the inner surface of the wall and at least the external surface of the drug layer located within the cavity. exit orifice and in fluid communication with the semipermeable portion of the wall; a drug layer located within the cavity [Hide claims]:

2. The dosage form of Claim 1 wherein the drug layer contains at least 40% by weight of drug based on the weight of the 3. The dosage form of Claim 1 wherein the expandable layer comprises an osmotic agent.

polyethylene oxides of less than 1 00,000 MW, hydroxyalkylcelluloses having number average molecular weights of between 4. The dosage form of Claim 3 wherein the flow-promoting layer comprises a material selected from hydrogels, gelatin, 9,500 and 1,250,000, and hydroxyalkyl alky1celluloses having number average molecular weights of between 80,000 to 850,000, and mixtures thereof. 5. The dosage form of Claim 1 wherein the flow-promoting layer is adapted to facilitate release of at least 80% of the drug in the drug layer to the environment of use.

6.An aritie of manufacture comprising a compressed drug composition overcoated with a flow-promoting layer. 7. The article of <u>Claim 6</u> comprising an expandable layer in direct or indirect contact with the drug composition and forming

a bilayer core with the drug composition, the bilayer core being overcoated with the flowpromoting layer. 8. The article of <u>Claim 7</u> wherein the flow-promoting layer comprises a material selected from hydrogels, gelatin,

polyethylene oxides of less than 1 00,000 MW, hydroxyalkylcelluloses having number average molecular weights of between 9,500 and 1,250,000, and hydroxyalkyl alkylcelluloses having number average molecular weights of between 80,000 to 9. The article of Claim 7 wherein the flow-promoting layer 1 5 comprises an hydroxypropyl cellulose. 850,000, and mixtures thereof.

semipermeable wall and a push layer, the method comprising interposing a flow promoting layer between the semipermeable 11. The method of Claim 10 wherein the flow promoting layer comprises a coating on the compressed drug composition 10.A method of facilitating the release of a drug from a dosage form comprising a compressed drug composition, a wall and the compressed drug composition.

prepared from a hydroxyalky cellulose and a lower alkanol. †

## Priority Number:

Application Number	Filec	Original Title
US2001000001116	2001-11-27	US2001000001116 2001-11-27 CONTROLLED DELIVERY OF ACTIVE AGEN
US1999000430837	1999-11-01	IS1999000430837 1999-11-01 CONTROLLED DELIVERY OF ACTIVE AGEN
US1998000106739P 1998-11-02	1998-11-02	

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